



FOR US POSTAL SERVICE DELIVERY:

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August 15, 2001

Michael M. Gottesman, M.D.
Deputy Director for Intramural Research
National Institutes of Health
Building 1, Room 114
Bethesda, MD 20892

**RE: Human Research Subject Protections Under Multiple Project Assurance
(MPA) M-1000**

**Research Project: Population Differences in the Insulin Sensitivity, Resting Energy
Expenditure, and Body Composition of Overweight Children and Children of
Overweight Parents**

Protocol Number: 96-CH-0101

Principal Investigator: Jack A. Yanovski, M.D., Ph.D.

Dear Dr. Gottesman:

The Office for Human Research Protections (OHRP) has reviewed your June 27, 2001 report regarding the above referenced research.

Based upon its review of your report, OHRP makes the following finding regarding the above-referenced research:

OHRP finds that the National Institute of Child Health and Human Development (NICHD) Institutional Review Board (IRB) has re-reviewed the research at its May 23, 2001 meeting and approved the research in accordance with the requirements of HHS regulations at 45 CFR 46.406 (research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition). Furthermore, OHRP finds that the NICHD IRB made and documented in the minutes of its meeting all findings required under HHS regulations at 45 CFR 46.406 and documented detailed, protocol-specific information justifying each required finding.

As a result of the above determination, effective immediately, enrollment of new subjects in the

above referenced research may resume and all research intervention and interactions stipulated by the IRB-approved protocol for previously enrolled subjects may proceed.

Please note that OHRP is still reviewing the documents submitted with your February 7, 2001 letter in response to OHRP's January 17, 2001 letter. You will be notified in writing of any additional comments that OHRP may have once this review is completed.

OHRP appreciates the commitment of your institution to the protection of human subjects.

Sincerely,

Michael A. Carome, M.D.
Director, Division of Compliance Oversight

cc: Dr. Ruth Kirschstein, Acting Director, NIH
Dr. Duane Alexander, Director, NICHD
Dr. Alan Sandler, Director, OHSR, NIH
Dr. Gilman Grave, Chair, IRB, NICHD, NIH
Dr. Jack Yanovski, NICHD, NIH
Dr. David Lepay, FDA
Dr. Greg Koski, OHRP
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Mr. George Gasparis, OHRP
Dr. Jeffrey M. Cohen, OHRP
Mr. Barry Bowman, OHRP